AUG 31 2000

K002333

Biosense Webster
a Johnson & Johnson company

Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA
Phone: 800-729-9010

SPECIAL 510(k) Summary
Biosense Webster
LASSO™ Deflectable Circular Mapping Catheter

Establishment information

Submitter Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA

Phone: 800-729-9010, ext. 8593
Fax: 909-468-3781
Registration number: 2029046 and 2020638

Contact Maria D. Ochoa
Regulatory Affairs
(909) 839-8593

Manufacturer Biosense Webster

General Device Information

PROPRIETARY DEVICE NAME:	Biosense Webster LASSO™ Deflectable Circular Mapping Catheter
Classification name:	Electrode recording catheter 21 CFR 870.1220
Common device name:	Deflectable mapping catheter
Classification	Class II

Predicate Devices

Biosense Webster CRISTA CATH™ Diagnostic Deflectable Tip Catheter, K953768

Biosense Webster HALO™XP Diagnostic Deflectable Tip Catheter, K953663

Device Description

Overview

The LASSO Mapping Catheter is similar in design to the predicate devices: the Biosense Webster CRISTA CATH Diagnostic Deflectable Tip Catheter and the Biosense Webster HALO XP Diagnostic Deflectable Tip Catheter. These catheters are legally marketed under FDA 510(k) K953768 and K953663, respectively. With their unique shapes, multiple ring electrodes, and ability of the distal tip to deflect, these catheters facilitate collection of simultaneous electrogram recordings with minimal repositioning of the catheter, which in turn can minimize procedure time. See attached photos at the end of this section.

Design

All three catheters conduct intracardiac signals through platinum-iridium ring electrodes to recording devices via a connector at the proximal end of the catheter. The LASSO mapping catheter is substantially equivalent to the predicates with the addition of the Nitinol formed "lasso" assembly at the distal tip. The platinum ring electrodes are located on the lasso assembly rather than on the catheter tip or shaft. Additionally, the LASSO Catheter utilizes a Pebax shaft rather than polyurethane shaft.

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Catheter Function

The Biosense Webster LASSO™ Deflectable Circular Mapping Catheter is substantially equivalent in function to the predicate devices. These catheters are designed to map structures of the heart. The LASSO catheter will be introduced via a compatible 8F sheath. The lasso shaped preformed loop can be positioned within various structures of the heart.

Specifications

The LASSO is a 7F catheter with usable lengths ranging from 60 to 125 centimeters. The LASSO has several "lasso" tip configurations ranging in from 10 to 25 mm; all "lasso's" are 3F size. The catheter has a high-torque shaft with a lasso-shaped tip section containing up to twenty (20) platinum electrodes that are easily seen under fluoroscopy. Identical to the predicate devices, there is a puller wire anchor at the distal end of the catheter tip, which in the LASSO, is located adjacent to the tip-lasso joint. The "lasso" tip is made of Nitinol, and is generally perpendicular to the distal end of the catheter.

Deflection

The LASSO and the predicate devices have high-torque shafts which allow the plane of the deflected curve (and the loop of the LASSO) to be maneuvered in order to facilitate accurate positioning. The flexible "lasso" tip retains its shape during deflection unless positioned in a sheath. Once removed from the sheath, the Nitinol "lasso" returns to its preformed shape.

Curve types

The catheter deflection curves will be available in "A" to "F" curves, which are identical to the deflection curves of legally marketed catheters such as the BWI Diagnostic Deflectable Tip Catheter (K892265).

Steering Operation

The piston in the handpiece is attached to an internal puller that controls the radius of the curvature of the distal portion of the catheter. When the piston is pushed forward, the radius of curvature of the distal section is reduced; when the thumbknob is pulled back, the radius of curvature is increased until the distal section is no longer deflected. This is substantially equivalent to the predicate device steering operation.

Packaging and Labeling

Packaging and labeling will be similar to the Biosense Webster's currently marketed deflectable diagnostic catheters.

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Indications for Use

The catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures, i.e. recording or stimulation only. The LASSO Catheter is designed to obtain electrograms in the atrial region of the heart.

Contraindications

- The Biosense Webster LASSO Circular Mapping Catheter has not been shown to be safe and effective for radio frequency (RF) ablation.
- Use of the catheter may not be appropriate for use in patients with prosthetic valves. A relative contraindication for cardiac catheter procedures is active systemic infection.
- The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle or patch.
- The retrograde approach is contraindicated because of risk of entrapping the LASSO in the left ventricle or valvular apparatus. The LASSO is not recommended for use in the ventricles.

Testing

Biocompatibility of the catheter has been verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the catheter when tested as an external communicating, blood contact, short duration (<24 hrs.) device.

Performance testing of the catheter included dimensional inspection, tensile strength, torque strength, and electrical tests. All testing of the product yielded acceptable results substantially equivalent to the predicate devices.

Summary of Substantial Equivalence

The Biosense Webster LASSO™ Deflectable Circular Mapping Catheter is substantially equivalent to the predicate device catheters. Equivalence has been established based on the results of testing catheter performance.

Similarity in labeling, design, materials and physical characteristics demonstrates that the devices are equivalent in design and function and that there is no difference in the safety and effectiveness of the LASSO to the predicate devices.

The Biosense Webster LASSO Deflectable Circular Mapping Catheter is substantially equivalent to the predicate devices in construction, materials, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Maria D. Ochoa
Regulatory Affairs Specialist
Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K002333
Biosense Webster Lasso™ Deflectable Mapping Catheter
Regulatory Class: II (two)
Product Code: DRF
Dated: July 31, 2000
Received: August 1, 2000

Dear Ms. Ochoa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the

under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4346. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Indications for Use Statement

510(k) No: K002333

Device Name: Biosense Webster LASSO™ Deflectable Circular Mapping Catheter

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 1. **OR** **Over the Counter Use** _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____